## 510(K) SUMMARY

AUG 28 2008

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| **Sponsor:** | Blackstone Medical, Inc.<br>1211 Hamburg Turnpike<br>Suite 300<br>Wayne, NJ 07470 |
| **Registration Number:** | 3004606875 |
| **Contact Person:** | Whitney G. Törning, Senior Director of Regulatory Affairs & Quality Assurance |
| **Telephone Number:** | 973.406.2838 |
| **Fax Number:** | 973.406.2938 |
| **Email:** | wtorning@blackstonemedical.com |
| **Submitter:** | Martin G. Sprunck<br>Regulatory Affairs Manager |
| **Manufacturer:** | Blackstone Medical, Inc.<br>90 Brookdale Drive<br>Springfield, MA 01104 |
| **Registration Number:** | 1225457 |
| **Trade Name:** | Blackstone PILLAR™ SA PEEK Spacer System |
| **Common Names:** | Intervertebral Body Fusion Device<br>Spinal Partial Vertebral Body Replacement Device |
| **Classification** | Class II |
| **Device Product Codes:** | MAX – Intervertebral Fusion Device with Bone Graft, Lumbar<br>MQP – Spinal Vertebral Body Replacement Device |
| **Regulation Numbers:** | 888.3080 – Intervertebral Body Fusion Device<br>888.3060 – Spinal Intervertebral Body Fixation Orthosis |

**Substantially Equivalent Devices:**

- Blackstone Medical, Inc. Construx PL/TL Partial VBR Spacers (K060350 SE 2-24-06)
- Blackstone Medical, Inc. Construx Mini (K051246 SE 6-14-05)
- Blackstone Medical, Inc. PILLAR Spacer System (K081177 SE 7-23-08)
- Surgicraft, Ltd. STALIF TT (K041617 SE 9-8-04 and K051027 SE 6-29-05)
- Surgicraft, Ltd., STALIF TT Intervertebral Body Fusion System (K073109 SE 6-4-08)
- Medtronic Sofamor Danek, Intrepid Spinal System (K080083 SE 4-10-08)

**Device Description:**

The Blackstone Medical, Inc. PILLAR SA PEEK Spacer System is comprised of a variety of implants manufactured from Polyetheretherketone (PEEK-OPTIMA® LT1), as described by ASTM F-2026, with tantalum markers as described by ASTM F-560. The implants are available in multiple footprint sizes, and a variety of heights and angles of lordosis. The implants incorporate integrated anterior screw holes to allow for medial placement of titanium screws that anchor to the vertebrae, as well as a titanium plate for securing the screws once in place. The superior and inferior surfaces of the implant have a pattern of ripples that provide increased stability and help prevent movement of the device.

**Intended Use / Indications for Use:**

When used as an Intervertebral Body Fusion System:

The PILLAR™ SA PEEK Spacer System is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels in the lumbar spine (L2-S1). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis at the involved levels. These patients may have had a previous non-fusion surgery at the involved level(s). The PILLAR™ SA PEEK Spacer System is intended for use with autograft.

The PILLAR™ SA PEEK Spacer System is intended for use with the four titanium alloy screws provided with the device. If the physician chooses to use fewer than four of the provided screws, then supplemental internal fixation must be used to augment stability. As an example, the supplemental internal fixation system that may be used is the Blackstone Medical, Inc. Spinal Fixation System (SFS).

Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the PILLAR™ Spacer System.

When used as a Partial Vertebral Body Replacement (VBR) System:

The PILLAR™ SA PEEK Spacer System is indicated for use in the thoracolumbar spine (T1-L5) for partial replacement (i.e. partial vertebrectomy) of a diseased vertebral body resected or excised for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The PILLAR™ SA PEEK Spacer System is also indicated for treating fractures of the thoracic and lumbar spine.

The PILLAR™ SA PEEK Spacer System is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column, even in the absence of

fusion for a prolonged period of time. The PILLAR™ SA PEEK Spacer System is intended to be used with autograft or allograft.

The PILLAR™ SA PEEK Spacer System is intended for use with the four titanium alloy screws provided with the device. If the physician chooses to use fewer than four of the provided screws, then supplemental internal fixation must be used to augment stability. As an example, the supplemental internal fixation system that may be used is the Blackstone Medical, Inc. Spinal Fixation System (SFS).

**Basis of Substantial Equivalence:**

Based on mechanical performance data and equivalence in configuration and indications for use, the Blackstone PILLAR SA PEEK Spacer System is substantially equivalent to the following devices, which have been cleared by FDA for the purpose of building a spinal implant construct in the non-cervical spine:

- Blackstone Medical, Inc. Construx PL/TL Partial VBR Spacers (K060350 SE 2-24-06)
- Blackstone Medical, Inc. Construx Mini (K051246 SE 6-14-05)
- Blackstone Medical, Inc. PILLAR Spacer System (K081177 SE 7-23-08)
- Surgicraft, Ltd., STALIF TT (K051027 SE 6-29-05 and K041617 SE 9-8-04)
- Surgicraft, Ltd., STALIF TT Intervertebral Body Fusion System (K073109 SE 6-4-08)
- Medtronic Sofamor Danek, Intrepid Spinal System (K080083 SE 4-10-08)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Blackstone Medical, Inc
% Ms. Whitney G. Törning
Senior Director of Regulatory Affairs and Quality Assurance
1211 Hamburg Turnpike, Suite 300
Wayne, New Jersey 07470

AUG 28 2008

Re: K081849
Trade/Device Name: Blackstone PILLAR™ SA PEEK Spacer System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: II
Product Code: MAX, MQP
Dated: July 30, 2008
Received: July 31, 2008

Dear Ms. Törning:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

**510(k) Number** (if known): K081849

**Device Name**: Blackstone PILLAR™ SA PEEK Spacer System

**Indications for Use**:

When used as an Intervertebral Body Fusion System:

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The PILLAR™ SA PEEK Spacer System is intended for use with the four titanium alloy screws provided with the device. If the physician chooses to use fewer than four of the provided screws, then supplemental internal fixation must be used to augment stability. As an example, the supplemental internal fixation system that may be used is the Blackstone Medical, Inc. Spinal Fixation System (SFS).

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K081849

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Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



Barbara Buchman

**(Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**

**510(k) Number** K081849